UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Ehab Sefen, ex rel United States of America pursuant to the Federal False Claims Act, 31 USC 3729 et seq. and individually under 31 USC 3730(h) 1076 Snyder Avenue Lansdale, Pa., 19446	**FILED UNDER SEAL**
vs.	Docket No.: 10-cv-02971
Animas Corporation 200 Lawrence Drive West Chester, PA 19380-3428. and Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, New Jersey	First Amended Qui Tam Complaint Pursuant to 31 U.S.C. Title 3729 and 3730

Plaintiff/Relator hereby files this First Amended Qui Tam Complaint on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq* in that it is a civil action arising under the laws of the United States and individually under 31 U.S.C. 3730(h). Plaintiff/Relator filed his original Qui Tam Complaint on or about June 17, 2010 and now amends such filing to incorporate an individual claim under 31 U.S.C. 3730(h).

Narrative Summary

Animas Corporation (Animas) is a company that specializes in making insulin pumps, used by people with diabetes. The company was acquired by Johnson and Johnson (J&J) on February 18, 2006. A Food and Drug Administration (FDA) Warning Letter # 05-PHI-03, (copy attached) was issued to Animas on February 24, 2005 (Warning Letter). The primary focus of the deficiencies cited in the Warning Letter

consisted of lack of proper quality control procedures to identify, track, and report corrective actions, patient complaints and computer validation systems.

Upon the acquisition of Animas in 2006, the FDA waived immediate enforcement of all mandates or conditions set out in the Warning Letter based on J&J promises to correct all deficiencies cited in the Warning Letter as more particularly described herein. Instead of correcting such deficiencies, J&J continued to manufacture and sell the insulin pumps and intentionally misrepresented to the FDA their own actions, or lack thereof, to correct the deficiencies, including the utilization of forged documents.

Based on the representations of J&J, the FDA did not do any follow up inspections until Relator contacted the Office of Compliance from the FDA and provided information to the FDA's supervisor of inspections, Mr Tamirillo, which resulted in an inspection on February 5, 2008. Relator was terminated on March 10, 2008. These voluntary disclosures by Relator to the FDA constitute a disclosure pursuant to the Federal False Claims Act, 31 USC 3729 et seq. Relator has heretofore filed supplemental disclosures pursuant to the Federal False Claims Act, 31 USC 3729 et seq.

I. Introduction

1. Ehab Sefen aka Mark Sefen ("Sefen" or "Relator") files this First Amended Qui Tam Complaint on behalf of the United States of America against defendants Animas Corporation and Johnson & Johnson for treble damages and civil penalties arising from the defendants' false statements and false claims in violation of the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* Relator brings this action based on his direct, independent, and personal knowledge.

2. As required by the False Claims Act, 31 U.S.C. § 3730(b)(2), Relator has provided to the United States by and through the Federal Drug Administration (FDA), Department of Justice (DOJ) (collectively "United States Government") and others, evidence and statements, both orally and through documents and other physical

evidence, of all material evidence and information related to the Complaint herein. These disclosures, supported by material evidence, were known to Relator at their filing establishing the existence of defendants' false claims. Relator was the original source of such information to the United States Government.

3. Relator's knowledge of the acts and fraud described herein were direct and independent and were voluntarily provided to the United States who had no knowledge of the fraud prior to receiving Relator's disclosures and evidence.

II. The Parties

A. Relator

4. Relator resides at 1076 Snyder Avenue, Lansdale, Pa. During the relevant times hereunder, Relator was employed by Defendant J&J on June 18, 2007. His position was Sr. Quality System Analyst for J&J's Animas subsidiary, and his main duties were (i) ensuring compliance of electronic records with FDA Regulations, (ii) oversight of the computer system known as the "Patient Complaint System" and (iii) assisting in various Computer Systems Validation (CSV) projects and corrective actions, one known as Project #CAPA 10-30. Initially, Relator received positive feedback from his supervisors.

B. Animas Corporation and Johnson & Johnson

5. Defendant Animas Corporation is a company that specializes in making insulin pumps, used by people with diabetes. The company was acquired by J&J on February 18, 2006. It is headquartered at 200 Lawrence Drive, West Chester, PA 19380-3428. Animas was expected to operate as a stand-alone entity reporting through LifeScan, Inc., a J&J subsidiary offering blood glucose monitoring systems. Defendant J&J is a New Jersey corporation with headquarters at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

III. Jurisdiction and Venue

6. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*

This Court has jurisdiction over this case pursuant to 31 U.S.C. §§ 3732(a) and 3730(b). This court also has jurisdiction pursuant to 28 U.S.C. § 1345 and 28 U.S.C. § 1331.

7. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because the acts proscribed by 31 U.S.C. §§ 3729 *et seq.* and complained of herein took place in this district, and is also proper pursuant to 28 U.S.C. § 1391(b) and (c), because at all times material and relevant, defendants transact and transacted business in this District.

IV. Summary Of Allegations

A. The Insulin Pump

8. Diabetes is a disease in which the body does not properly control the amount of sugar in the blood. As a result, the level of sugar in the blood is too high. This disease occurs when the body does not produce enough insulin or does not use it properly.

9. Insulin infusion pumps are medical devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)]. An insulin pump can improve quality of life in a way that's different from taking multiple injections. Pumpers are intended to provide patients with new levels of freedom, flexibility and control. Animas had approval from the FDA for a number of pump types. They include the following:

a. The Animas OneTouch® Ping™ acts like a pancreas and is an insulin pump which releases small amounts of rapid-acting insulin to keep blood glucose levels steady between meals and during sleep. The Animas Ping is a wireless diabetes therapy system, although the pump functions can be used wirelessly or manually. At meal or snack time, the patient can tell the pump to deliver the amount of insulin needed to match the grams of carbohydrate in the food that is eaten, just like a healthy pancreas. The OneTouch Ping insulin pump is about the size of a cell phone. It has a color screen, several buttons, a cartridge filled with rapid-acting insulin and a compact motor that pushes precise amounts of insulin from the cartridge through a thin plastic

tube and into the body (this is called an infusion set).

b. The IR 1200 is the smallest, full-feature insulin pump. The IR 1200, Animas' third generation of insulin pumps, has several features including low basal insulin delivery, largest screen display, CarbSmart, long battery life, non-volatile RAM and waterproof at 12 feet for 24 hours.

c. The Animas 2020 is an insulin pump that carries 200 units of insulin and can be connected to an infusion set following the luer standard. Its predecessor was the Animas IR1250. The system was designed to be personal and comes in five different colors, features a color screen and allows the user to have custom alarm tones. To improve treatment the system can save instructions to use when its user has a sick day and up to 500 rules set by the user on how to act on different occasions (such as when eating a certain food type).

The Animas insulin pumps are hereinafter referred to as the Devices

III. Chronology

A. The FDA Warning Letter

10. A FDA Warning Letter, # 05-PHI-03 (copy attached as Exhibit "A") was issued to Animas on February 24, 2005. J&J acquired Animas in January 2006. The FDA did not perform any inspection at Animas since the Warning Letter was issued and waived immediate enforcement with all mandates and conditions cited in the based on J&J's express promise that all deficiencies would be corrected.

11. In summary, the FDA warned that the Devices were adulterated under section 501(h) of the ACT [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulations, all as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The significant deviations included, but are not limited to, the following:

a. Failure to adequately establish and maintain procedures for implementing corrective and preventive actions, (known as "CAPAs") which include requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential problems, including the proper reporting of such complaints to the FDA, as required by 21 CFR 820.100(a)(1).

b. Failure to adequately establish and maintain procedures for implementing CAPAs, which includes requirements for verifying or validating the CAPAs to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).

c. Failure to adequately establish and maintain procedures to control the manufacture and sale of devices that does not conform to specified requirements, as required by 21 CFR 820.90(a).

d. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming devices after rework, to ensure that the devices meet its current approved specifications, as required by 21 CFR 820.90(b)(2).

12. In performing or attempting to perform his duties as Sr. Quality System Analyst, Relator discovered the fraud alleged herein was on a much larger scale than reported in the Warning Letter, because changes to the computer systems were not documented on paper, but rather kept in electronic records that can easily be changed without leaving a trace. For this reason, the FDA has established requirements set forth in 21 CFR part 11 to ensure electronic records that reside on computer systems are protected.

B. Defendant's Non-compliance and lack of quality in Computer System Validation (CSV) and Change Control

13. Defendants, contrary to express requirements and certifications, has not complied with its system validation and quality control measures as follows:

***a. CAPA file for CSV*:** Corrective Action and Preventative Action file #CAPA 10-30. J&J set up a new computer system to track CAPA open files, in which they changed this CAPA file number to a new number and gave it a new date to avoid being cited by FDA for delay on closing CAPA files. J&J did not have adequate standard operating procedures ("SOP") for computer system validation ("CSV"), and did not establish adequate conversion despite the fact that it was one of the main observations from Corporate Quality.

The violations in CAPA file 1030 were very significant since it includes failure to validate the majority of critical software around the company including validation of Patient Complaint.

b. Change and Control Practices. J&J never followed "Change In Control" practices required by FDA when changes were made related to CSV which was an FDA regulatory requirement. This led to an endless cycle of non-compliance in which patients provided complaints to Animas about injury or faulty devices, which was then stored on a non-validated (non-compliant) computer system that was not secured. Changes could occur to the system without a trace and patient complaints were often not reported to the FDA. Instead, patients were routinely told that the product did not cause their injury and the device operates correctly.

The design of the devices also changed without documenting the change or any traceability of such change, and no FDA approval was or is obtained. As a result, the patients are using a device no longer approved by the FDA. This process deceives the patients and saves money for the company that should have been spent on regulatory filling and compliance cost.

***c. Use of Spreadsheets - Non compliance and failure to follow Standard Operating Procedure*:** J&J often used non-validated spreadsheets in various areas of Complaint Processing. These non-validated Spreadsheets included Patient Medical and Personal Records that goes directly against HIPPA regulations. In

addition, spreadsheets were also used in almost all areas across the company such as Compliance, Quality Control, Design, Manufacturing, Document Control. The company had no intention to comply with 21 CFR Part 11 of the FDA regulations; and continued to use non validated systems.

C. Project Manager and IT Manager insisted on Use of Forged Documents:

14. Relator attended a meeting on August 21, 2007 with IT Manager Nadine Magic and Project Manager Joan Morrissey. Morrissey presented the documents that she intended to use for the validation of the Patient Complaint System to demonstrate that the validation of the new upgraded system was properly accomplished.

15. Relator objected, stating that these documents were actually more than two years old and the system had significant changes since then and would have more changes due to the upgrade.

16. Relator objected to certifying that these documents accurately represented that the Patient Complaint System was properly validated to comply with FDA regulations. Relator advised that the documents which Morrissey intended to use were not accurate and did not represent the accurate status of the system. There was pressure during the meeting to use those documents as is. On the same day, Relator met with Donna Pyne (QA and CSV specialist) and explained his concern regarding those documents and asked her to join their team to ensure Quality Assurance representation during the project; which was a requirement by FDA regulations.

17. Relator's supervisor had knowledge of the use of forged documents and gave her approval to use the same. Relator met with his supervisor during a scheduled one-on-one meeting and invited Pyne in the meeting. Both Relator and Pyne explained their concern that these documents can not be accepted as they are misleading, and the majority of the content can not be incorporated in the validation system.

18. Subsequent to this meeting, a Core Team Meeting was held on September 14, 2007 with all team members for two hours including Nadine Magic, Joan

Morrissey, Donna Pyne, Rita McIntyre and Relator. The Project Manager changed the roles and responsibilities of the team members for the project for no reason. As a result of this realignment, IT was to have oversight and control of certain documents of the project, which effectively meant that, indirectly, Relator was not being allowed access to information that he was responsible for in the Patient Complaint Computer System.

19. Relator's main duties as Sr. Quality System Analyst was the oversight of the computerized "Patient Complaint System". The management team included his supervisor, Director of Compliance and IT manager Nadine Magic. They requested that he incorporate and "sign off" on documents, certifying to their accuracy, even though he believed that they were not accurate and were a misrepresentation of system functionality. Relator refused to do so.

D. Retaliation Against Relator For His Complaints and Objections

20. Immediately after this meeting, Relator had a conversation with the project manager Morrissey who threatened Relator, stating *"let things go or we will get someone else to do your job"*. Later, at another meeting she said *"Let things go, and we will get you back in the clique"*.

21. Thereafter, Relator had a series of meetings with human resources (HR). The objective was to force Relator to scale back his standards and disregard following FDA regulations or loose his job. Relator's supervisor stated that he brought very valuable expertise to the company but he needed to *"scale back his standards since the company is not a very large company like the ones he used to work for in the past; and the company did not have the resources to comply fully with FDA requirements in the same scale that he used to see in his past experience."*

22. A second meeting with HR was held in a conference room the following day and included Joan Morrissey, saying *"let things go or we will get someone else to do your job"*. Relator was told during this meeting from Project Manager (Ms. Joan Morrissey) that he has excellent knowledge and called him the "the quality king in the

company") but asked Relator to trust her. Morrissey repeated that Relator needed to trust her and not to worry. Relator believed that this meant that he needed to let things go, trust them and sign on forged documents, or suffer the consequences of loosing his job.

23. On the same day after the second meeting with HR on September 21, Donna Pyne also declined to agree with the proposed Project Plan developed by Project Manager and indicated that the initial Validation Plan that Relator developed is more compliant with FDA regulations, and requested that Relator take the initiative and develop his own version.

24. Relator then received a Performance Improvement Plan (PIP) from HR eleven days after contacting Corporate Quality on October 26, 2007, during a meeting with HR Justine Smith, and his supervisor Rita McIntyre. The PIP had false accusations that did not have any foundations that were a pretext for the Company retaliating against Relator. Relator then contacted the office of compliance from the FDA. These contacts resulted in FDA conducting an inspection on February 5, 2008. Relator was terminated on March 10, 2008.

IV. CAUSES OF ACTION

A. Violation of The Federal False Claims Act

25. Title 31 of the United States Code, section 3729(a) provides that any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

. . . . . .

(7) knowingly makes, uses or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

. . . . . .

is liable to the United States Government for a civil penalty of not less than $5,500.00 and not more than $11,000.00, plus 3 times the amount of damages which the Government sustains because of the act of that person.

26. The false claims submitted by J&J and Anamis consist of (i) continuing to sell the Devices knowing that they were not in compliance and (ii) falsely representing to the FDA that the deficiencies in the Warning Letter had been corrected.

27. Infusion pumps are a covered device under the provisions set out in the Medicare Manual Chapter 280.14, entitled "Infusion Pumps", which states that Infusion pumps are medical devices used to deliver solutions containing parenteral drugs under pressure at a regulated flow rate.

28. The device cost is nearly $10,000 each and the company had achieved more than 100 million in revenue in the last quarter of 2007 from sales of the devices; and those revenues were projected an increase of 25% year over year due to the acquisition of J&J.

29. Based on the allegations set forth herein, Defendants have violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1) in that they knowingly presented and caused to be presented to the United States Government a false or fraudulent claim for payment or approval.

30. Based on the allegations set forth herein, Defendants have violated the False Claims Act, 31 U.S.C. §§ 3729(a)(2) in that Defendants have and has also knowingly made and used or and caused to be used a false record or statement to get a false or fraudulent claim paid or approved by the Government;

31. Based on the allegations set forth herein, Defendants have violated the

False Claims Act, 31 U.S.C. §§ 3729(a)(3) in that they have conspired to defraud the Government by getting a false or fraudulent claim allowed or paid;

WHEREFORE, Relator respectfully requests this Court to enter judgment against Defendants, as follows:

(a) That the U.S. be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims and fraud alleged within this Complaint, as the Civil False Claims Act, 31 U.S.C. §§ 3729 *et seq.* provides;

(b) That civil penalties be imposed for each and every false claim that defendant presented to the U.S. and/or its grantees;

(c) That post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the relator necessarily incurred in bringing and pressing this case;

(d) That the Court grant permanent injunctive relief to prevent any recurrence of the False Claims Act for which redress is sought in this Complaint;

(e) That the Relator be awarded the maximum amount allowed to them pursuant the False Claims Act;

(f) That any funds received by the United States or any Agencies thereof, in whatever form, be treated as an alternate remedy to which Relator is entitled to his statutory share of under the False Claims Act.

Count II

Sefen v. J&J and Animas

Violation of 31 USC 3730(H)

32. Plaintiff re-alleges and incorporates Paragraphs 1 through 31 above as if fully set forth herein.

33. 31 USC 3730(H) provides as follows:

> h) Any employee who is discharged, *demoted,* suspended, *threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer* because of

> lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole. Such relief shall include reinstatement with the same seniority status such employee would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees. An employee may bring an action in the appropriate district court of the United States for the relief provided in this subsection.

34. For reasons stated above, J&J and Animas have violated section 31 USC 3730(H) by retaliating against Relator by terminating his employment because of his actions described herein.

WHEREFORE, Sefen requests judgement as to Complaint II of this Complaint by awarding damages including compensatory damages, punitive damages, emotional distress, attorney's fees, interest and costs, as well as injunctive relief as is deemed appropriate by the Court.

Begelman, Orlow & Melletz

Date: November 18, 2010

By:

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vs.	**CERTIFICATION OF SERVICE**
Animas Corporation and Johnson & Johnson	

FILED
NOV 18 2010
MICHAEL E. KUNZ, Clerk
By Dep. Clerk

I, Ross Begelman, Esquire, of full age, hereby certify that on November 18, 2010, I caused the original of Plaintiff's First Amended Qui Tam Complaint and this Certification of Service to be filed with the Clerk of the United States District Court for the Eastern District of Pennsylvania and further, caused to be served upon:

Margaret Hutchinson, Esq.
United States Attorney's Office
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Eric Gill, Esq.
United States Attorney's Office
Assistant United States Attorney
615 Chestnut St., Suite 1250
Philadelphia, PA 19106

Eric H Holder, Jr.
US Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

by New Jersey Lawyers Service.

I certify that the foregoing statements made by me are true. I am aware if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

Begelman, Orlow & Melletz

By: _____
Ross Begelman, Esquire

Date: November 18, 2010

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by New Jersey Lawyers Service.

I certify that the foregoing statements made by me are true. I am aware if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

Begelman, Orlow & Melletz

By: _____
Ross Begelman, Esquire

Date: November 18, 2010